

APPENDIX 7
Pharmaceutical Product Stewardship Policy Comparison:
Proposed Legislation in WA State, Proposed Ordinance in Alameda County, CA, and B.C.’s Medications Return Program

Each policy requires drug producers selling specified medicines in the jurisdiction to provide, finance, and promote a safe, convenient program for return and disposal of leftover medicines.

Policy Component	WA State Proposed Secure Medicine Take-back Legislation	Alameda County CA Proposed Safe Drug Disposal Ordinance	British Columbia Enacted Medications Return Program
Background Information	<p>Analysis of 2011/2012 session bill SSB 5234, “An Act related to providing safe collection and disposal of unwanted drugs from residential sources through a producer-provided and funded product stewardship program”.</p> <p>WA population ~ 6.8 million.</p>	<p>Analysis of Alameda County proposed ordinance as of July 6, 2012 that was passed unanimously (5-0) in a first reading and vote on July 10th by Alameda County Board of Supervisors. A final reading and vote on the ordinance is scheduled for July 24, 2012.</p> <p>Alameda County population ~1.5 million.</p>	<p>Analysis of underlying regulation and the resulting Medications Return Program. The B.C. Recycling Regulation was enacted in 2004 as a consolidation of an original 1997 regulation. Pharmaceuticals were added to the list of covered products in 1999 and the Post-Consumer Pharmaceutical Stewardship Association (PCPSA) was formed by drug producers to operate the province’s sole program plan.</p> <p>B.C. population ~ 4.57 million.</p>
1. Medicines accepted for return (covered drugs)	<ul style="list-style-type: none"> Prescription medicines (legend) and over-the-counter medicines (non-legend), sold in any form. Includes brand name and generic drugs. Includes legally prescribed controlled substances <p><u>Exempted drugs:</u></p> <ul style="list-style-type: none"> vitamins or supplements; herbal based remedies and homeopathic drugs; cosmetics or personal care products that are regulated as both over-the-counter drugs and cosmetics , such as toothpaste, sunscreen, and medicated shampoos; drugs for which producers provide a take-back program as part of a FDA managed risk evaluation and mitigation strategy; biologic drugs where producers already provide a take-back program; pet pesticides, i.e. collars, powders, shampoos. 	<ul style="list-style-type: none"> Prescription medicines (legend). Includes brand name and generic drugs. <p><u>Exempted drugs:</u> Same exemptions as the WA legislation, plus the following –</p> <ul style="list-style-type: none"> over-the-counter (non-prescription) medicines; legally prescribed drugs that are controlled substances are excluded from the ordinance, except for provisions for support to law enforcement agencies offering medicine take-back (see 3. Who Pays For and Provides the Program); medical devices, and their component parts, or a covered drug contained in or on medical devices and component parts; soap, laundry detergent, bleach household cleaning products. 	<ul style="list-style-type: none"> Prescription medicines, sold in all dosage forms Over-the-counter medicines, sold in oral dosage forms Natural Health Products = vitamins and supplements, sold in oral dosage forms <p>The regulation requires the program to accepts all unused and expired drugs, except the following <u>exempted drugs:</u></p> <ul style="list-style-type: none"> unused or expired drugs from a hospital; contact lens disinfectants; antidandruff shampoo or products; antiperspirants; antiseptic or medicated skin care products; sunburn protectants; mouthwashes; fluoridated toothpastes.

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2. Users of the program (covered entities)	<ul style="list-style-type: none"> Residents, including single and multiple family residences. People returning drugs from locations where household drugs are unused, unwanted, disposed of, and abandoned “such as hospice services, boarding homes, schools, foster care, day care, and where people or their pets reside on a temporary or permanent basis.” <u>Does not include:</u> waste from hospitals, clinics, pharmacies, airport security, drug seizures by law enforcement, businesses, or other nonresidential or business sources identified by the Board of Pharmacy. 	<ul style="list-style-type: none"> “Residential generators” = single and multiple family residences People returning drugs from locations where household drugs are unused, unwanted, disposed of, and abandoned. (no defined list) <u>Does not include:</u> wastes from business and nonresidential sources similar to language in WA legislation. 	<p>Regulation:</p> <ul style="list-style-type: none"> Residential sector <u>Does not include:</u> unused or expired medicines from hospitals, health provider offices, or provincial health care systems. <p>Program Operations:</p> <ul style="list-style-type: none"> In addition to take-back from residents, the program also collects medicines from the public in special needs sites – currently, 5 community hospitals in remote areas and 5 retirement/care facilities.
3. Who pays for and provides the program?	<ul style="list-style-type: none"> No visible fee to consumers allowed at time of sale or time of collection. Primarily financed and provided by drug producers selling covered drugs in Washington, as part of doing business. <p>Producers are required to pay for all administrative and operational expenses, including:</p> <ul style="list-style-type: none"> secure collection containers and shipping supplies for required minimum number of collection sites; mailers and mailings if a mail-back system is used; transportation (including law enforcement escort if required); disposal of medicines at high temperature incineration facility; education and program promotion; program administration; costs of state agency oversight. 	<ul style="list-style-type: none"> No specific fee to consumers allowed at point-of-sale or point-of-collection. Primarily financed and provided by drug producers selling covered drugs in Alameda County, as part of doing business. <p>Producers are required to pay for all administrative and operational expenses, including costs of:</p> <ul style="list-style-type: none"> collection, transportation, and disposal of unwanted medicines; recycling or disposal, or both, of packaging collected with the unwanted medicines costs of agency oversight; For prescription drugs that are controlled substances, producers are only required to provide support to any law enforcement agencies in the county that have, or later agree to have, a collection program. The support shall include providing: 	<ul style="list-style-type: none"> No fee to consumers allowed at time of collection. The regulation is silent on fees at point of sale. Currently there is no “Eco-Fee” at point of sale for pharmaceuticals. Primarily financed and provided by producers of pharmaceuticals sold in the province. Producers of pharmaceuticals must have an approved take-back plan in order to sell medicines in British Columbia. <p>Producers are required to pay for:</p> <ul style="list-style-type: none"> costs of collecting and managing products. The Recycling Regulation does <u>not</u> require producers to pay for costs of agency oversight. Currently the B.C. Ministry of the Environment provides oversight through their budget.

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		<ul style="list-style-type: none">Total costs to producers <u>cannot exceed</u> \$2.5 million per year, annually adjusted for inflation. (roughly two pennies per container of medicines sold, and less than 0.07% of the approximately \$4 billion in annual medicines sales in WA.)Collection sites volunteer their staff time. Producer not required to pay for staff time at voluntary collection sites, but producers may offer/negotiate incentives for collectors.State and local governments must help promote safe storage of medicines and use of the take-back program through existing education methods.Dept. of Health may establish fees on producers or program operators to recover agency expenses for administration and oversight.	<ul style="list-style-type: none">a collection kiosk with signagetechnical support up to and including an appropriate person to provide onsite assistance with sorting and separating controlled substances at no cost to the law enforcement agency.Alameda Co Dept. of Enviro Health may establish a schedule of fees on producers to recover agency expenses for administration and enforcement.	
4. Take-back System Requirements (Producer Responsibilities)	4A. Collection System	<ul style="list-style-type: none">Collection system must be convenient and adequately serve both urban and rural residents.Minimum number of drop-off collection sites provided statewide – at least 1 per county plus 1 per city with pop. > 10,000 (=114 sites).Drop-off sites would participate voluntary at pharmacies, law enforcement offices, hospitals, fire stations, as allowed by state and federal regulations for handling covered drugs.Pre-paid return mailers must be available if drop-off sites not available in a specific county or city.	<ul style="list-style-type: none">Collection must be provided in all areas of the county that are reasonably convenient to the public and adequate to serve the needs of county residents.Collection sites may be placed at appropriate retail stores, but retailers are not required or mandated to host collection sites.Mail-back may be used.Each program must accept all unwanted covered products regardless of who produced them, unless excused by Dept.	<p><u>Regulation:</u></p> <ul style="list-style-type: none">Collection facilities for pharmaceuticals are not specified, but must comply with operating and reporting requirements for return facilities in the B.C. Hazardous Waste Regulation (1988). <p><u>Program Operations:</u></p> <ul style="list-style-type: none">Program has 1,033 collection sites at pharmacies that voluntarily participate.95% of pharmacies in the province choose to participate. They collect medicines and store them until the container is full, then contact the program for pick-up within 7 days.

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4. Take-back System Requirements (Producer Responsibilities)	4B. Handling of Medicines and Packaging & Protection of Patient Information	<ul style="list-style-type: none">Producers’s plan must explain how unwanted medicines will be safely and securely tracked.Producers’ plan must explain how patient information will be kept secure during collection, transportation, and disposal.Producers’ plan must explain how drugs will be separated from packaging to the extent possible, and how drug packaging will be recycled, to the extent possible.	<ul style="list-style-type: none">Producer’s plan(s) must explain how unwanted medicines will be safely and securely tracked.No specific language on protection of patient information.Programs(s) shall encourage residents to separate unwanted drugs from their original containers, when appropriate, prior to collection and disposal.	<p><u>Regulation:</u></p> <ul style="list-style-type: none">Producer’s plans must explain how products will be managed safely. No specific language on pharmaceutical handling; Canada does not have similar regulations for controlled drugs as U.S.Producers must collect and manage product containers. No specific language for pharmaceutical packaging or protection of patient information. <p><u>Program Operations:</u></p> <ul style="list-style-type: none">Pharmacists accept medicines from consumers and dump pills out of their containers into collection bin. Liquids, creams, and pills in blister packs remain in their packaging.Containers are recycled.
	4C. Disposal of Medicines	<ul style="list-style-type: none">Disposal of medicines must be at a properly permitted hazardous waste facility or a properly permitted in-state solid waste incineration facility (currently only Spokane WTE facility qualifies under WAC 173-434).Programs may petition WA Dept. of Ecology to use disposal technologies that provide superior environmental and human health protection.	<ul style="list-style-type: none">Disposal of medicines must be at a medical waste or hazardous waste facility.Programs may petition Alameda Co Dept Environmental Health to use disposal technologies that provide superior environmental and human health protection.	<p><u>Regulation:</u></p> <ul style="list-style-type: none">Regulation does not define the specific disposal method. Requires safe management of pharmaceuticals in compliance with a pollution prevention hierarchy and the Environmental Management Act’s provision, which regulates hazardous waste disposal and operation of incinerators. <p><u>Program Operations:</u></p> <ul style="list-style-type: none">Collected medicines are sent to a licensed solid waste incineration facility in Alberta, Canada.

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5. Education Requirements (Producer Responsibility & Government Agencies)	<ul style="list-style-type: none">Producers must promote safe storage of medicines and how to use the take-back program to consumers, pharmacists, retailers, and health care professionals “so that collection options are widely understood by customers, pharmacists, retailers of covered products, and health care practitioners”Producers must provide materials to pharmacies, health care facilities, and others.Producers must provide a website, toll-free number, and materials.Producers must evaluate the effectiveness of its education efforts as part of their annual report.A survey of residents to measure awareness and program convenience must be conducted at least every four years.	<ul style="list-style-type: none">Producers must promote the program to residents, pharmacists, drug retailers, and health care practitionersProducers must provide education and outreach materials to pharmacies, such as signage and written materials to be provided to consumers at time of purchase.Producers must provide a website and toll-free number for residents.Producers must describe their methodology for evaluating education and outreach activities as part of their annual report.	<p>Regulation:</p> <ul style="list-style-type: none">Producers are required to make consumers aware of the product stewardship program and collection locations. The regulation requires the producer’s plan to describe an education plan, but does not define any required methods or target audiences. <p>Program Operations:</p> <ul style="list-style-type: none">Program has a website, and links from other governmental and pharmacy-related websites. Info is available by phone through a BC Recycling “Hotline”. Posters and brochures are provided to pharmacies.Since 2007, the program has improved its education/outreach through media and increased distribution of bookmarks and materials. The amount of collected medicines increased 250% in 3 years as public awareness increased from 31% in 2007 to 48% in 2010.Of the 48% aware of the pharmacy return program in 2010, three-quarters (75%) had used it the last time they disposed of medicines. The survey measured a large corresponding decline in the practice of throwing medicines in the garbage.

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6. Administration	6A. Who is defined as a “drug producer”	<p>The legislation applies to all producers of covered drugs sold in the state of Washington.</p> <p>A Producer is any of the following:</p> <ul style="list-style-type: none">• Legal brand owner, brand name owner, co-brand owner of covered drugs, or manufacturer of generic covered drugs.• Importer of covered drugs when the legal brand owner or manufacturer has no physical presence in US.• Wholesaler who is not a brand owner, but who elects to fulfill the responsibilities of a producer for that covered drug. <p>Producer does <u>not</u> include:</p> <ul style="list-style-type: none">• a retailer who puts its store label on covered drugs.• a pharmacist who compounds a drug product for a patient. <p>Annual list of producers:</p> <ul style="list-style-type: none">• Each drug wholesaler selling covered drugs in the state must annually provide a list of producers of covered drugs to the WA Board of Pharmacy.	<p>The ordinance applies only to a producer whose covered drug is sold or distributed in Alameda County.</p> <p>A Producer of a covered drug sold in Alameda County shall be determined as meaning one of the following:</p> <ul style="list-style-type: none">• The person who manufacturers and who sells, offers for sale, or distributes a covered drug in Alameda County under their own name or brand.• The owner or licensee of a trademark or brand, whether or not the trademark is registered, if there is no person who sells or distributes the covered drug in the county.• If there is no person who is a producer under the previous two bullets, then the producer of that Covered Drug is the person who brings the Covered Drug into Alameda County for sale or distribution. <p>Producer does <u>not</u> include:</p> <ul style="list-style-type: none">• a retailer who puts its store label on covered drugs• a pharmacist who compounds a prescribed drug product for a patient.	<p>Under the B.C. Recycling Regulation, a product producer is any of the following:</p> <ul style="list-style-type: none">• Manufacturer of the product that sells, offers for sale, distributes or uses commercially the product in B.C. under the manufacturer's own brand,• Person who is not the manufacturer of the product but is the owner or licensee of a trademark under which a product is sold, distributed or used commercially in B.C.• Person who imports the product into B.C. for sale, distribution or commercial use .

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6. Administration	6B. How do drug producers work together?	<ul style="list-style-type: none">Legislation creates the WA Medicine Return Corporation, a non-profit product stewardship organization that is managed and financed by drug producers. All producers of covered drugs sold in WA must participate.Medicine Return Corporation is managed by a Board of Directors composed of representatives of producers of covered drugs, at a minimum:<ul style="list-style-type: none">2 brand name prescription drugmakers,2 generic prescription drugmakers,2 over-the-counter drugmakers,2 biotechnology sector drugmakers, and4 members of the Legislature – ex-official, non-votingThe Corporation’s Board develops a proposed product stewardship plan to be reviewed by WA Board of Pharmacy.The Corporation’s Board determines a method for “equitably apportioning costs” among drug producers. This method is reviewed and approved by the WA Board of Pharmacy. Each producer is required to remit payment to the Corporation.As part of plan development, the Medicine Return Corporation must hold a public hearing and solicit comments from stakeholders.	<ul style="list-style-type: none">Producers must operate a take-back program individually or jointly with other producers orEnter into an agreement with a product stewardship organization to operate a take-back program on the producer’s behalfIf more than one producer will be involved in a proposed product stewardship program, then the product stewardship plan must include a fair and reasonable manner for allocating costs among the participating producers, such that the portion of costs paid by each producer is reasonably related to the amount of covered drugs sold by the producer in the county.	<p>Regulation:</p> <ul style="list-style-type: none">The regulation requires producers to provide an approved program, or to appoint an agent to provide the program. <p>(No further detail about how producers work together or apportion costs.)</p> <p>Program Operations:</p> <ul style="list-style-type: none">In December 1999, producers formed the Post Consumer Pharmaceutical Stewardship Association (PCPSA) made up of the:<ul style="list-style-type: none">Canada’s Research-Based Pharmaceutical Companies (Rx&D), andCanadian Generic Pharmaceutical Association (CGPA), andCanadian self-care association (over-the-counter, vitamins, supplements).The PCPSA has a 9 member Board of Directors.An Executive Director reports to the Board and is responsible for operations, finances, communications, and administration.Currently 109 companies participate in the PCPSA.The PCPSA invoices each company annually. Rates for each company are determined by the Board of Directors based on prescriptions dispensed and/or sales of consumer health products.

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6. Administration	6C. Reporting & Evaluation	<ul style="list-style-type: none">• Annual report required from producers that reports pounds of medicines collected, education methods used, total costs, and other info about program operations.• An annual evaluation of education effectiveness is required in the producer’s annual report.• Producers must annually solicit comments from health care providers/facilities, pharmacists, local govts, law enforcement, and citizens on satisfactions with the program’s services.• At least every four years, producers must conduct a survey of residents to measure awareness and program convenience.	<ul style="list-style-type: none">• Annual report required from producers that reports pounds of medicines collected, education methods used, total costs, and other info about program operations.	<ul style="list-style-type: none">• Annual report required from Producers that reports pounds of medicines collected, education methods used, and other info about program operations.
	6D. Performance Standards	<ul style="list-style-type: none">• No recovery rate requirements.• Has convenience standard and education requirements.• Producers are required to solicit feedback from communities on satisfaction with services, see 6C Reporting & Evaluation.	<ul style="list-style-type: none">• No recovery rate requirements.• Has convenience standard and education requirements.	<p>Regulation:</p> <ul style="list-style-type: none">• B.C. Recycling Regulation requires stewardship plans for any product to achieve a 75% recovery rate within a reasonable time, or another recovery rate established by the director. <p>Program Operations:</p> <ul style="list-style-type: none">• No required recovery rate on amount of medicines collected.• Program has goal of maintaining minimum of 90% pharmacy participation rate.• Program is targeting education to districts with lower return rates.

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6. Administration	6E. Oversight & Enforcement (Government Responsibilities)	<ul style="list-style-type: none">• WA Board of Pharmacy reviews and approves the Medicine Return Corporation’s plan. Any proposed changes to the approved plan must be approved by the Board.• Producers must submit an updated plan for review every 4 years.• WA Department of Ecology consults with Board of Pharmacy on environmentally sound disposal.• WA Association of Sheriffs and Police Chiefs consults with Board of Pharmacy on security measures.• Board of Pharmacy licenses the product stewardship program, adopts rules, invites comments on satisfaction with services, and may establish performance standards.• Board of Pharmacy enforces the law and may administer penalties for non-compliance to any individual producer or to the take-back program.• Board of Pharmacy may audit the Medicine Return Corporation and may inspect any facilities of the program.	<ul style="list-style-type: none">• Alameda Co Dept. of Environmental Health reviews and approves the producer’s plan(s). Any proposed changes to the approved plan must be approved by the Dept.• Producers must submit an updated plan for review at least every 3 years.• As part of plan review, the Dept. holds a public hearing.• If the Dept. rejects a producer(s) plan, and also rejects a revised plan, then the Dept. may develop and impose its own plan.• Dept. of Environmental Health enforces the ordinance and may administer penalties for non-compliance to any individual producer or to a take-back program.	<ul style="list-style-type: none">• B.C. Ministry of the Environment reviews and approves the producer’s plan(s), and enforces the regulation.• Producers must submit a revised plan for review, or notify the Ministry that there are no changes, at least every 5 years.

Sources of information:

- WA State Legislation, Substitute Senate Bill 5234, online at <http://apps.leg.wa.gov/documents/billdocs/2011-12/Pdf/Bills/Senate%20Bills/5234-S.pdf>.
- Alameda County draft ordinance, as of 07/06/12, online at http://www.acgov.org/board/bos_calendar/documents/DocsAgendaReg_07_10_12/GENERAL%20ADMINISTRATION/Regular%20Calendar/Miley_Safe_Drug_Disposal_Ordinance.pdf.
- B.C. Environmental Management Act - Recycling Regulation 449/2004, 2004, online at http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/449_2004. B. C. Hazardous Waste Regulation 63/88, 1988, online at http://www.bclaws.ca/EPLibraries/bclaws_new/document/ID/freeside/63_88_05. B.C. Medications Return Program 2010 Annual Report, online at: <http://www.medicationsreturn.ca/ar2010.pdf>